

Message Text

UNCLASSIFIED

PAGE 01 STATE 012316

12

ORIGIN HEW-06

INFO OCT-01 EA-10 ISO-00 OES-05 RSC-01 /023 R

66614

DRAFTED BY: DHEW/FDA/JRWEINROTH MD

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

EA/ANP:MMICHAUD INFO

----- 077910

R 172354Z JAN 75

FM SECSTATE WASHDC

TO AMCONSUL SYDNEY

INFO AMEMBASSY CANBERRA

UNCLAS STATE 012316

E.O. 11652: NA

TAGS: ETRD, TBIO, AS

SUBJ: RECALL OF MEDICAL DEVICE-BENNETT MONITORING SPIROMETER
AND ALARM

REF: SYDNEY 0068; STATE 01981

1. FDA ADVISES THAT NO RPT NO RECALL OF BENNETT DEVICES HAS YET
OCCURRED. FINAL DECISION REGARDING RECALL STILL PENDING.

2. EXTENT OF PRESENT ACTION IS TO ASSURE THAT CONSIGNEE
IN RECEIPT OF LETTER FROM FIRM TO DISTRIBUTORS WHICH ADVISES
THAT USERS OF THE DEVICES SHOULD ENSURE INTEGRITY OF BOTH
EXPIRATORY DIAPHRAGM VALVE AND ITS CONNECTING RUBING WHEN
CONNECTED TO ANY PRESSURE OR VOLUME VENTILATOR PRIOR TO
AND DURING USE OF SUCH APPARATUS. CONSIGNEE MAY OR MAY NOT
HAVE BEEN RECIPIENT OF WARNING LETTER. KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 17 JAN 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE012316
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750020-0172
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750141/aaaabjrv.tel
Line Count: 48
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 1
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 75 SYDNEY 0068, 75 STATE 01981
Review Action: RELEASED, APPROVED
Review Authority: MorefiRH
Review Comment: n/a
Review Content Flags:
Review Date: 07 MAY 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <07 MAY 2003 by SilvaL0>; APPROVED <25 Nov 2003 by MorefiRH>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF MEDICAL DEVICE-BENNETT MONITORING SPIROMETER AND ALARM
TAGS: ETRD, TBIO, AS, US, BENNETT RESPIRATION PRODUCTS INC
To: SYDNEY
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006